

REMARKS

Claims 1, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Rieke (USPN 3,452,743).

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rieke (USPN 3,452,743) as applied to claim 1 above, and further in view of Takehara et al (2002/0022787 A1) in view of Duong et al (6,740,518 B1).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rieke (USPN 3,452,743) as applied to claim 1 above, and further in view of Baura et al (6,561,986 B2).

Claims 4-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rieke (USPN 3,452,743) as applied to claim 1 above, and further in view of Alt (6,829,503 B2).

Claim Objection

Claim 8 is objected to for reciting “one or electrical currents”. Applicant agrees with the Examiner that claim 8 should recite “one or *more* electrical currents”, and so amends claim 8 herein. Because the amendment resulted from an inadvertent omission, the omitted term was apparent to the Examiner, and did not affect the scope of the Examiner’s search, applicant submits that the correction does not affect the scope of the claim or of the Office’s prior art search. Therefore, applicant respectfully submits that the Examiner suggested amendment does not require an additional search by the Office.

Claim Rejections – 35 U.S.C. § 102

Claims 1, 7 and 8 are rejected under 35 U.S.C. § 102(b) as being anticipated by Rieke (3,452,743; ‘Rieke’). However, applicants submit that the Office’s assertions are contrary to the express descriptions in Rieke.

A claim is anticipated only if *each and every* element as set forth in the claim is found, either *expressly or inherently* described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of CA*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131 (emphasis provided).

Applicants’ independent claim 1 recites,

providing a *first set* of injection electrodes and a *second set* of measurement electrodes;

positioning members of the first set of electrodes...and thereby...define injection vectors...between two or more injection electrodes;

positioning members of the second set of electrodes...to define measurement vectors...between the injection electrodes, [and]

deriving from *each of different pairs of the injection and measurement vectors* two or more electrical bio-impedance values

Applicants' claim expressly recites providing and positioning *plural* injection electrodes (e.g., at least 80 and 88 in FIG. 3 at right) and measurement electrodes (e.g., at least 82 and 90 in FIG. 3), defining *plural vectors* therebetween (e.g., 'I' injection and measurement vectors in FIG. 3), and deriving plural bio-impedance values from each of *different pairs* of the plural vectors (see also paragraphs [0043] and [0044]). Likewise, applicants' specification clearly describes that

a medical practitioner uses at least one pair of injection electrodes to inject electrical current into the body and another pair, or more, of measurement electrodes to measure electrical voltage produced as a result of electrical current flowing through the body tissue. (Paragraph [0028])

Rieke Expressly Limits Its Device to Only a Single Pair of Symmetrically Placed Active Electrodes for Applying a Current and Measuring an Impedance vs. Applicants' Multiple Sets of Electrodes.

By contrast, Rieke depicts and expressly describes only a single pair of electrodes for applying and measuring impedance. "A more specific object is to provide a body impedance measuring device that uses *a single pair of electrodes* for applying the measuring current *and* for measuring the impedance," (Rieke, col. 1, lines 69-72; Emphasis provided).

Consistent with Rieke's expressed specific object, each of FIGS. 2-5 indicated by the Office Action, depict only a single pair of electrodes (identified in Rieke as 'A1' and 'A2') for applying the measuring current and for measuring the impedance.

With regard to FIG. 2 (right), Rieke describes, "only active electrodes A1 and A2 are applied," (col. 6, lines 26-27). With regard to FIG. 3 (below), Rieke describes only a "pair of active electrodes A1 and A2," (col. 6, lines 62-63). With regard to FIG. 4 (below), Rieke states "the fact that the preferred measurement current path is limited to a central channel 60 between active

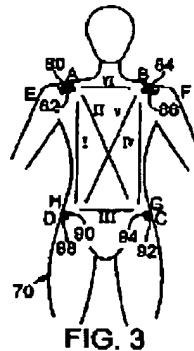


FIG. 3

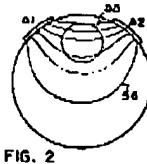


FIG. 2

electrodes A1 and A2," (col. 6, lines 70-72), and that "[t]he measuring current flows between active electrodes A1 and A2," (col. 7, lines 5-6).

Thus, Rieke fails to expressly or inherently disclose a *set* of "two or more" injection electrodes and a second *set* of plural measurement electrodes, and instead expressly states its object as providing a device "that uses a *single pair* of electrodes for applying a measuring current and for measuring the impedance".

Rieke's 'Focus' and 'Guard' Electrodes are Expressly Excluded from Any Symmetrical Impedance Measurement Current Flow Path, While Rieke's Asymmetrical Current Paths Do Not Flow Between Injection Electrodes, and Flow Through Disparate Regions and/or Spaces of a Subject's Anatomy

Although Rieke depicts and describes using other 'guard' and 'focus' electrodes, Rieke expressly describes that these are *not used for measurement* in symmetrical electrode arrangements, and are configured entirely differently from applicants' in asymmetrical electrode arrangements.

With regard to **symmetrical arrangements**, Rieke describes FIGS. 3 and 4 as examples. As to FIG. 3, "There is current flow 58 between the guard G and focus F electrodes but *this is not measured*. In addition, there is flow between F1 and F2 and *this is not measured either*," (col. 6, lines 52-54; Emphasis provided)

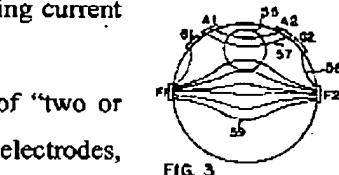


FIG. 3

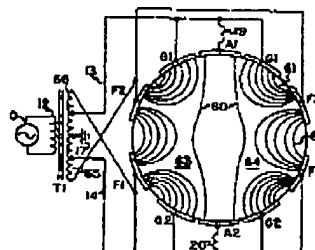


FIG. 4

Likewise, as to FIG. 4 (right), Rieke describes "two pairs of focus electrodes F1 and F2 and two pairs of guard electrodes G1 and G2 are employed along with the pair of active electrodes A1 and A2," (col. 6, lines 60-63). However, as noted above and depicted at right, Rieke clarifies that the "measurement current path is limited to a central channel 60 between active electrodes A1 and A2," (col. 6, lines 70-72). The 'guard' and 'focus' electrodes do not inject a current or measure a voltage, and therefore do not disclose applicant's sets of injection and/or measurement electrodes.

In Figure 5 (right), "only active electrodes A and guard electrodes G is [sic] shown," wherein "the guard electrodes control the geometry of the current path between the active electrodes," (col. 7, lines 20-25).

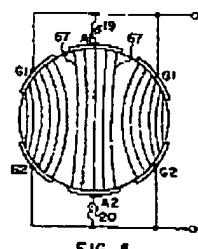


FIG. 5

Providing a definitive summary with regard to FIGS. 2-5, Rieke definitively states:

With symmetrical arrangement of electrodes, the guard and focus electrodes do not carry any part of the current that flows between the active electrodes across which the impedance is measured but instead, they are used to control and influence the

current path between the active electrodes. (Col. 2, lines 66-71;
Emphasis provided)

Thus, in the described and depicted embodiments cited in the Office Action, Rieke expressly contradicts the Office's assertions, and fails to expressly or inherently disclose *any* of the several features shown above, recited in at least applicants' independent claim 1.

With regard to **asymmetrical arrangements**, Rieke describes that electrical current does not flow between the active electrodes A1 and A2, due to a modification to the circuit.

Another technique that is useful and available for discriminating between signals by subtraction employs the 100 kilocycle portion of the bridge. This involves *reversing the polarity of one of the primary windings* such as 19 which is *connected to an active electrode*. The guard electrodes G1 and G2 would be located unsymmetrically so that current flows, for example, *from A1 to the G2 pair and from A2 to the G1 pair*, (col. 8, lines 33-36).

As described here in Rieke, current flows from an active electrode (e.g., one which "apply[s] the measuring current") to a pair of guard electrodes, *not to the other active electrode*. This arrangement is unlike Rieke's symmetrical arrangement wherein "current...flows between the active electrodes," (see citation above), and is also unlike applicants' independent claim 1. According to claim 1, "electrical currents flow *between two or more injection electrodes*" and the measurement electrodes "define measurement vectors relating to electrical voltages produced in response to the electrical currents flowing *between the injection electrodes*".

Additionally, Rieke describes that the asymmetrically placed electrodes produce and measure different measurement paths from one another, thus measuring different regions within an anatomical space and/or different anatomical spaces of the subject.

The currents from A1 and A2 would not be the same. The path from A1 may include the desired body organ and function such as the heart and the path from A2 may exclude most of the heart signal but include much of the interfering respiratory signal. (col. 8, lines 36-41)

Rieke's asymmetrically placed electrodes are expressly intended to cause current to flow *through different regions and/or spaces* (e.g., 'organs and functions') of a subject's anatomy, to provide a reference for Rieke's intended subtractive method for discriminating signals.

By contrast, applicants' claim 1 recites 'the injection and measurement vectors defin[e] *an anatomical space* of the mammalian tissue", "deriving...bio-impedance values...indicating the electrical bio-impedance...within *a region of the anatomical space*", and "analyzing

the...values to detect...indications of fluid movement, accumulation, or depletion affecting *the region in the anatomical space*".

While it should be clear that Rieke fails to *expressly* disclose several features of applicants' claim 1, it should be likewise clear that Rieke also fails to *inherently* disclose several features of claim 1.

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999).

Rieke fails to 'make clear that the missing descriptive matter is necessarily present' therein. Thus, applicants respectfully submit that Rieke fails to expressly or inherently disclose several features of at least applicants' independent claim 1, and the Office Action fails to establish a *prima facie* case for the asserted 35 U.S.C. § 102 rejection thereof.

Inasmuch as the claims 7 and 8 depend from and include the distinct features of independent claim 1, applicant respectfully submit that the Office Action likewise fails to establish a *prima facie* case for the asserted rejections of claims 7 and 8.

In light of the facts in the record as discussed above, applicants request withdrawal of the rejections asserted in the 23 June 2009 Non-Final Office Action under 35 U.S.C. § 102 with regard to all claims so rejected.

Claim Rejections – 35 U.S.C. § 103

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rieke as applied to claim 1 above, and further in view of Takehara et al in view of Duong et al.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rieke as applied to claim 1 above, and further in view of Baura et al.

Claims 4-6 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rieke as applied to claim 1 above, and further in view of Alt.

Each of the asserted 35 U.S.C. § 103(a) rejections relies initially and essentially upon the Office's assertions with regard to applicants' independent claim 1 under 35 U.S.C. § 102. The secondary references do not overcome the failures of Rieke, and are not asserted for that purpose.

For at least this reason, applicants respectfully submit that claims 2, 3, 4-6 and 9-11 include at least one feature that is not taught or fairly suggested by the references of record, and that no *prima facie* case under 35 U.S.C. § 103(a) exists in the record with respect to these claims. Therefore, applicants request withdrawal of the rejections asserted in the 23 June 2009 Non-Final Office Action under 35 U.S.C. § 103(a) with regard to all claims so rejected.

CONCLUSION

Accordingly, applicant requests entry of the above amendment and consideration of the application on the merits. The Examiner is encouraged to telephone the undersigned at (503) 226-1191 if it appears that an interview would be helpful in advancing the case.

Respectfully submitted,

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I hereby certify that this correspondence is being transmitted to the U.S. Patent and Trademark Office via facsimile number 571-273-8300 on the following date: August 5, 2009

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